

REMARKS

The present invention relates to an anti-tumor agent and a method for treating a tumor.

This Amendment is filed in response to the non-final Office Action dated December 13, 2007, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance is respectfully submitted to be proper.

Claims 1-3 and 16-17 were rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over "The Anti-tumor Effect to Stomach Cancer by Benzyl Alcohol," Meeting of Japan Surgical Society on April 12-14, 2000, issued on March 10, 2000, PP-1457 ("Reference PP- 1457") and Head, K.A. Alternative Medicine Review, 1998, vol. 3, No. 3, pages 174-186 ("Head"), in view of U.S. Patent No. 6,448,287 B1 ("Casciari").

Particularly, the Office Action took the position that Reference PP-1457 teaches administration of 200-500µg and 1000µg benzyl alcohol to stomach cancer cells, and therefore suggested that benzyl alcohol may be used as an anti-tumor agent. The Office Action conceded that Reference PP-1457 does not teach or suggest administering benzyl alcohol in combination with vitamin C for the treatment of stomach cancer.

However, according to the Office Action, Head cures the deficiency in Reference PP-1457 because Head assertedly suggests the addition of vitamin C with existing chemotherapy regimens to treat most cancers.

With respect to the recited dose, it has been asserted that Casciari provides evidence that vitamin C can be administered in a ratio of 1:1 to 3,500:1 and preferably 10:1 to 100:1 with another drug. Thus, according to the Examiner, in the absence of showing unexpected results commensurate in scope with the claims, the method as recited in the present claims are assertedly *prima facie* obvious.

The amendments and how they respond to the rejections set forth in the Office Action are explained below in detail.

In the present Amendment, claim 1 has been amended to recite that “the ratio of benzyl alcohol to vitamin C is about 1:10”. The specification in the paragraph bridging pages 7 and 8, for example, supports the amended recitation of claim 1. Entry of the Amendment is respectfully submitted to be proper. Upon entry of the Amendment, claims 1 - 3, 16 and 17 will be all the claims pending in the application.

More specifically, independent claim 1 now recites a method for treating a tumor comprising the step of administering a composition containing benzyl alcohol at a dose of 1 mg - 50 mg/cm³ of tumor volume in combination with vitamin C, wherein the ratio of benzyl alcohol to vitamin C is 1:10, wherein said dose is sufficient to cause cells of said tumor to become necrotic, and wherein said tumor is a stomach tumor.

Applicant respectfully submits that amended claim 1 is patentable over Reference PP-1457 and Head, even in view of Casciari. First, the references alone or combined do not teach or suggest each limitation recited in claim 1. Thus, one skilled in the art would not have combined

the teachings of Reference PP-1457 and Head in view of Casciari to arrive at the present method as recited in claim 1. Casciari is clearly directed to the combination of lipoic acid and ascorbic acid. Further, Casciari does not teach the administration of vitamin C in a ratio of 1:1 to about 3500:1 with “another drug”. Rather, Casciari teaches “[t]he preferred ratio of ascorbic acid to lipoic acid is from about 1:1 to about 3500:1. (See column 2, lines 17-19). Casciari states that the objective is to provide a method for treating cancer wherein lipoic acid or combined therapy is used in combination with another therapy. Lipoic acid is preferably used in combination with ascorbic acid (vitamin C). The Office Action conceded that there is no motivation to combine vitamin C and benzyl alcohol based on the teaching in Casciari and Reference PP-1457, because Casciari is drawn solely to the combination of lipoic acid and vitamin C, and does not teach, suggest, motivate, or provide other reason to substitute lipoic acid with benzyl alcohol. Thus, Casciari does not teach or suggest the use of vitamin C with benzyl alcohol nor the use of vitamin C and benzyl alcohol in a specific range. Accordingly, Casciari does not cure the deficiency of Reference PP-1457 and Head with respect to the recited ratio of benzyl alcohol to vitamin C as recited in the present claims.

Even if Head, Reference PP-1457, and Casciari could be combined, Applicant respectfully submits that claim 1 is patentable over the prior art documents in view of the amendment to claim 1, and in further view of Dr. Takeyama's Declaration under 37 C.F.R. § 1.132, filed in the U.S. Patent and Trademark Office on April 14, 2006. Applicant submits that the results provided in the Declaration are commensurate in scope with the present claims. Reconsideration of the Declaration evidence and withdrawal of the rejection is respectfully submitted to be proper.

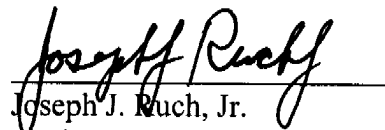
Claims 2, 3, 16 and 17 depend from claim 1 directly or indirectly, and therefore are patentable over the Head Reference PP-1457 and Casciari for at least the reasons mentioned above with respect to claim 1. Accordingly, Applicant respectfully submits that withdrawal of the rejection of claims 1 -3, 16 and 17 is proper.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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